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| 09/970,458 | 10/02/2001 | Jan Seppala | S63.2-10087 | 9618 |

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VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

BAXTER, JESSICA R

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/04/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/970,458

Applicant(s)

SEPPALA ET AL.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 7, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,950,227 to Savin et al.

Regarding claim 1, Savin discloses a stent delivery system comprising: a stent delivery catheter (catheter 12), the stent delivery catheter having a stent mounting region, the stent mounting region having an inflatable portion (balloon 14); a stent disposed about the stent mounting region (stent 16), the stent having an unexpanded position and an expanded position (Column 4 lines 16-19); at least one stent retaining sleeve having first and second ends (sleeves 18, 20), the first end being attached to the stent delivery catheter (detents 22, 24), the at least one stent retaining sleeve disposed about at least a portion of the stent in the unexpanded position (FIG. 1), the stent retaining sleeve being constructed and arranged to retract toward the attached first end when the stent is expanded (FIG. 2 and Column 5 lines 27-37).

Regarding claim 7, Savin discloses that the first end is attached proximally of the stent (detent 24).

Regarding claim 8, Savin discloses that the first end is attached distally of the stent (detent 22).

Regarding claim 9, Savin discloses that the at least one stent retaining sleeve comprises proximal and distal stent retaining sleeves (sleeves 18, 20), each having first and second ends, the first end of the proximal stent retaining sleeve being attached to the stent delivery catheter proximally of the stent (detent 24) and the first end of the distal stent retaining sleeve being attached to the stent delivery catheter distally of the stent (detent 22).

3. Claims 1, 2, 3, 5, 6, 7, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,387,118 to Hanson.

Regarding claim 1, Hanson discloses a stent delivery system comprising: a stent delivery catheter (catheter 14), the stent delivery catheter having a stent mounting region, the stent mounting region having an inflatable portion (inflatable portion 16); a stent disposed about the stent mounting region (stent 12), the stent having an unexpanded position and an expanded position; at least one stent retaining sleeve having first and second ends (sleeves 30 and 32), the first end being attached to the stent delivery catheter, the at least one stent retaining sleeve disposed about at least a portion of the stent in the unexpanded position (FIG. 1), the stent retaining sleeve being constructed and arranged to retract toward the attached first end when the stent is expanded (Column 4 lines 21-46).

Regarding claim 2, Hanson discloses that the at least one stent retaining sleeve is ribbed (Column 4 lines 21-24).

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Regarding claim 3, Hanson discloses that the at least one stent retaining sleeve is pleated (Column 4 lines pleats 42, 44).

Regarding claims 5 and 6, Hanson discloses that the at least one stent retaining sleeve is comprised of at least two materials (Column 3 line 66 –Column 4 line 9).

Regarding claim 7, Hanson discloses that first end is attached proximally of the stent (sleeve 30).

Regarding claim 8, Hanson discloses that first end is attached distally of the stent (sleeve 32).

Regarding claim 9, Hanson discloses that the at least one stent retaining sleeve comprises proximal and distal stent retaining sleeves (sleeves 30 and 32), each having first and second ends, the first end of the proximal stent retaining sleeve being attached to the stent delivery catheter proximally of the stent (sleeve 30) and the first end of the distal stent retaining sleeve being attached to the stent delivery catheter distally of the stent (sleeve 32).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savin et al. '227 in view of U.S. Patent No. 6,168,617 to Blaeser et al.

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Savin discloses the claimed invention except for the at least one stent retaining sleeve having a plurality of openings. Blaeser teaches that the stent retaining sleeves may be provided with a plurality of holes to enhance their flexibility (Column 6 lines 9-13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Savin with a plurality of openings in order to increase the flexibility of the device.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savin et al. '227 in view of U.S. Patent No. 5,445,646 to Euteneuer et al.

Savin discloses the claimed invention except for the proximal and distal stent retaining sleeves overlapping. Euteneuer teaches that the proximal and distal retaining sleeves overlap to form a seal (Column 6 lines 44-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Savin with the overlapping stent retaining sleeves in order to provide a seal between the sleeves.

Response to Arguments

7. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731


JRB

September 2, 2003


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700